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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,043	02/22/2002	Oliver Yoa-Pu Hu	39297-174169	8602

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,043	HU ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-15 and 17-23* is/are pending in the application.

4a) Of the above claim(s) *3 and 17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-9, 12-15* is/are rejected.

7)☒ Claim(s) *10 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment filed October 25, 2005 is acknowledged. Claims 16, 24 and 25 are canceled. Claims 1, 3, 5-15 and 17-23 are pending. Claims 17-23 remain withdrawn from consideration as drawn to non-elected inventions. Claim 3 fails to recite the compound swertiamarin. Accordingly, claim 3 is withdrawn from consideration as drawn to non-elected inventions. Claims 1 and 5-15, wherein swertiamarin is the cytochrome P450 3A (CYP3A) inhibitor under consideration, remain under consideration.

An objection to the disclosure set forth in the last Office Action is withdrawn following an amendment to claim 9 and cancellation of claim 25.

Claims 12-15 were objected to under 37 CFR 1.75(c) for failing to further limit the subject matter of a previous claim.

Claims 12-15 are now drawn to method of use claims. The objection is withdrawn.

In the last Office Action claims 1, 3, 5-9 and 12 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims in co-pending applications S.N. 10/079416 and S.N. 10/948206.

Applicants choose to hold these provisional rejections in abeyance.

Claims 1, 3 and 6-15 were rejected under 35 U.S.C. 112, second paragraph, for issues of indefiniteness. It was asserted in the last Office Action claim 1 is written as a compound claim. A composition claim recites a carrier.

Although claim 1 has been amended such that an intended use is recited, it remains drawn to a cytochrome P450 3A (CYP3A) inhibitor as a free base or

pharmacologically acceptable salt, a compound. Only claim 6 is a proper composition claim.

This rejection of claim 1 of record is maintained.

The rejection of claims 7-15 as lacking clarity is withdrawn. The claims have been amended either to recite a "method" or dependency from a method of use claim.

Claims 7-9 and 12 were rejected as lacking clear antecedent basis in the independent claim from which they depend.

This rejection of record of claims 7-9 and 12 is withdrawn. The dependencies of the claims have been changed, and they are now method claims.

In the last Office Action claims 1, 5 and 6 were rejected under 35 U.S.C. 102(b) as being anticipated by Yamahara et al., Journal of Ethnopharmacology (abstract). It was asserted Yamahara teaches the compound swertiamarin as prepared in a pharmaceutical composition for oral administration.

The rejection of claim 5 is withdrawn following an amendment to the claim such that it is now a method claim.

Applicants argue Yamahara does not teach the free base or pharmaceutically acceptable salt of swertiamarin and that it inhibits the enzymatic activity of CYP3A. Applicants urge the reference is only directed to the anticholinergic activity of *Swertia japonica*, fractionated components and the CYP3A inhibitor element of the pharmaceutical composition is not taught.

The intended use of swertiamarin, i.e., as an inhibitor of CYP3A enzymatic activity, in a pharmaceutical composition confers no patentable weight to the claim.

Applicants are not entitled to procure claims based on discovery that a known composition can be adapted to a new use. In re Hack, 114 USPQ 161 (CCPA 1957). As previously asserted, claim 1 remains directed to a compound claim. Yamahara teaches a pharmaceutical composition comprising swertiamarin. One skilled in the art would reasonably expect swertiamarin to be present as a free base.

The rejection of claims 1 and 6 under 35 U.S.C. 102(b) is maintained.

Subsequent to the cancellation of claims 16, 24 and 25, the rejection of record under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make or practice the invention, is moot.

Claims 12-15 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, Applicants must convey with reasonable clarity, as of the filing date, that Applicants were in possession of the claimed invention. The issue of a lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996),

(a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that Applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventors had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventors constructed an embodiment or performed a process that met all the limitations of the claims and determined that the invention would work for its intended purpose. Applicants may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Applicants were in possession of the claimed invention as a whole.

Applicants may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics that provide evidence that Applicants were in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when

coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicants were in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicants have not conveyed possession of the invention with reasonable clarity to one skilled in the art. There are no working examples directed to patients having any cancer or, in particular, intestinal, hepatic, an adenocarcinoma or hepatoma. Applicants have not provided any working examples that would describe to one of ordinary skill in the art an embodiment that meets all the limitations thereof. Applicants have not described with sufficient clarity an inhibition of cytochrome P450 3A enzymatic activity in

the claimed patient population comprising administering swertiamarin. Sufficient guidance to support predictable operability of the invention to one of ordinary skill in the art is absent.

Claims 5 and 7-15 appear to be free of the prior art.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

January 2, 2006

Phyllis G. Spivack

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PHYLLIS SPIVACK
PRIMARY EXAMINER